

PATENT
Attorney Docket No. PC25047A US

REMARKS

I. Status

Claims 1-17 are pending in the application. Claims 15-17 are currently withdrawn. Claim 1 is currently amended to correct certain errors of a typographical nature, delete certain text, and for increased clarification, which is discussed in greater detail below. Claims 2-4 are currently amended for increased clarification.

Claims 1 and 4 stand rejected under 35 U.S.C. § 112, ¶2. Claims 1-14 stand rejected under 35 U.S.C. § 102(b) over Kath *et al.*, WO 99/40061 ("WO '061"). Claims 1-14 also stand rejected under 35 U.S.C. § 102(b) over Brown *et al.*, WO 98/38167 ("WO '167"). Claims 1-4 and 8-11 stand rejected under obviousness-type double patenting over claims 1-5 and 11 of US 6,403,587. Applicants respectfully traverse the foregoing rejections.

II. Miscellaneous

It is kindly requested that the Examiner initial the Supplemental Information Disclosure statement filed February 20, 2004 and send a copy of it to Applicants with the next communication.

III. Restriction Requirement

Applicants are being required to elect one of the following groups pursuant to 35 U.S.C. § 121:

- I. Claims 1-14, drawn to heteroaryl-hexanoic acid amide derivatives, classified in class 544, subclass 353+.
- II. Claims 15-17, drawn to method of use or treatment, classified in class 514, subclass 249.

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At the outset, Applicants respectfully traverse the restriction requirement. MPEP § 803 states that the two criteria for a proper requirement for restriction are (1) the inventions ~~must~~ be independent or distinct as claimed, and (2) there must be a serious burden on the Examiner if restriction is required.

Here, the Examiner has not shown that there would be a serious burden on the Examiner if restriction were not required. Rather, the Examiner merely generally states at page 2 of the Office Action, "the process of using the product as claimed can be practiced with another materially different product. . ." The Examiner has not indicated with specificity, however, how a search for all of the claims as originally filed would present a serious burden on the Examiner. In particular, the Examiner has not indicated with specificity how a search for the methods of treating or preventing defined by the claims of Group II would be less burdensome given the fact that claims 15-17 incorporate the features of the compounds of claim 1. In view of the Examiner's broad and general characterization regarding the "serious burden" imposed on the Examiner, the restriction requirement appears improper. Applicants respectfully request removal of the restriction requirement at this time.

Nevertheless, to advance the prosecution of the present application and to be fully responsive to the present restriction requirement, Applicants hereby affirm the election of Group I (claims 1-14) with traverse for examination purposes. In addition, Applicants hereby affirm the election of the species of Example 1 as required by the Examiner.

Non-elected claims 15-17 are currently withdrawn without prejudice to pursuing the subject matter of such claims in any continuing application, such as, e.g., a continuation application, a divisional application, etc.

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Pursuant to MPEP § 821.04, if the compound and composition claims of elected Group I are subsequently found allowable, Applicants respectfully request that the claims of Group I (claims 15-17), which depend from or otherwise include all the limitations of the allowable compound and composition claims, be rejoined.

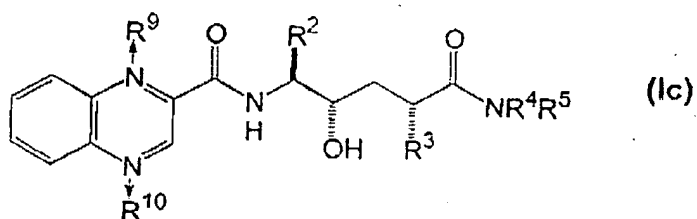
IV. Claims 1 and 4 Are Definite

Claims 1 and 4 stand rejected under § 112, ¶2. Applicants respectfully traverse the rejection.

In particular, the Examiner asserts that claim 1 is indefinite because the variable Y is not defined in the structure shown in claim 1. In response, claim 1 is currently amended to delete the definition of Y, which was originally presented in error. Such error was made unintentionally and in good faith. In addition, claim 1 is currently amended to delete the definitions of X and R¹², both of which refer to the formula presented in the definition of Y. In addition, the specification is correspondingly amended to delete the definitions of Y, X, and R¹². No new matter is being added by the current amendments.

With regard to claim 4, the Examiner asserts that the two nitrogen atoms in the quinoxaline ring have four bonds instead of three, which supposedly renders the claim indefinite. In response, claim 4 is currently amended to define a compound according to claim 1, wherein R¹ is quinoxalinyll, R⁷ is hydrogen, and L is a bond as shown in formula (Ic)

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wherein R^2 , R^3 , R^4 , and R^5 are as described in claim 1; and R^9 and R^{10} are each independently oxygen or electron pairs, with the proviso that at least one of R^9 and R^{10} are oxygen if R^3 is (C_1-C_6) alkyl substituted with R^8-L-O- and R^8 is hydrogen. Support for the amendment to claim 4 can be found throughout the specification, e.g., at originally filed claim 4. In particular, support for the amended formula Ic with regard to the relationship between the nitrogen atoms on the quinoxaline ring and R^9/R^{10} can be found throughout the specification, e.g., at page 9 - page 13 of the specification. In just one example, the compound 1-oxy-quinoxaline-2-carboxylic acid [4(R)-carbamoyl-1(S)-(3-fluoro-benzyl)-2(S),7-dihydroxy-7-methyl-octyl]-amide disclosed at page 10 is representative of the compounds of formula Ic. No new matter is being added by the current amendments.

In view of the foregoing remarks, claims 1 and 4 are definite and removal of the present rejection is respectfully requested at this time.

V. Claims 1-14 Are Novel Over WO '061

Claims 1-14 stand rejected under § 102(b) over WO '061. Applicants respectfully traverse the rejection.

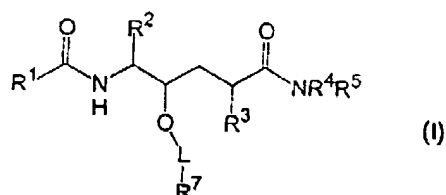
Present claim 1 is novel over WO '061 at least because WO '061 does not disclose each and every element of present claim 1. Present claim 1 defines a compound of the formula (I):

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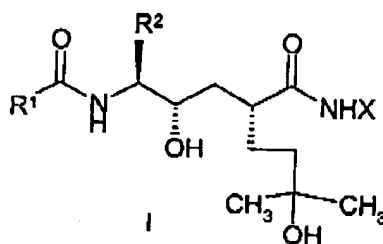
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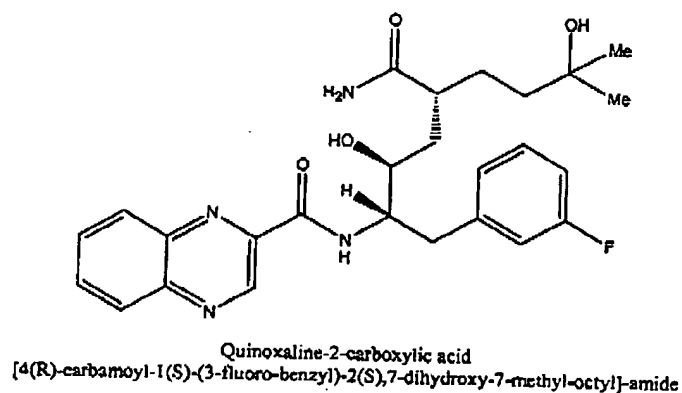


and the pharmaceutically acceptable forms of such compounds. Claim 1 defines L as being a bond or -O-(CR¹³R¹⁴). R⁷ is defined as being a variety of groups including hydrogen. The first proviso of claim 1 states that if L is a bond, both R⁷ and R⁸ may not be hydrogen unless R¹ is (C₂-C₉)heteroaryl substituted with one or more groups of oxygen.

In contrast, WO '061 discloses certain compounds of the general formula:



In particular, the Examiner asserts that the following species being exemplary of the disclosed genus of WO '061 anticipates the presently disclosed compounds:



Present claim 1 is novel over WO '061 at least because the compounds disclosed by WO '061 are within the scope of the first proviso of present claim 1. The compounds of the general formula of WO '061 have a hydroxyl group corresponding in position to the $-O-L-R^7$ group of the presently disclosed general formula. To arrive at the hydroxyl group of WO '061, L would be a bond and R^7 would be hydrogen. Further, the compounds of the general formula of WO '061 have a $[(Me)_2OH]C-CH_2-CH_2-$ group corresponding in position to R^3 of the presently disclosed general formula. To arrive at the $[(Me)_2OH]C-CH_2-CH_2-$ group of WO '061, R^3 would be (C_1-C_{10}) alkyl substituted with R^8-L-O- , wherein L would be a bond and R^8 would be hydrogen. In summary, to arrive at the compounds disclosed by WO '061 including the species cited by the Examiner, L would be a bond and R^7 and R^8 would be hydrogen.

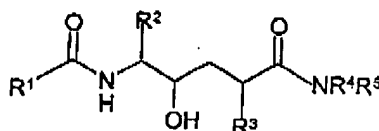
But, as mentioned above, present claim 1 has the proviso stating that if L is a bond, both R^7 and R^8 may *not* be hydrogen unless R^1 is (C_2-C_9) heteroaryl substituted with one or more groups of oxygen. (Emphasis added). As is apparent from the cited species, the quinoxaliny group disclosed by WO '061 is not substituted with one or more groups of oxygen. Indeed, none of the compounds disclosed by WO '061 have a (C_2-C_9) heteroaryl group substituted with one or more groups of oxygen when both R^7 and R^8 are hydrogen, which is required by the proviso of present claim 1. Thus, claim 1 is novel over WO '061 for at least this independent, patentably significant reason.

Claims 2-13 are novel over WO '061 at least by virtue of their direct or indirect dependency from novel claim 1. Claim 14 is novel over WO '061 at least by virtue of it defining an amount of a compound according to novel claim 1. Therefore, removal of the present rejection is respectfully requested at this time.

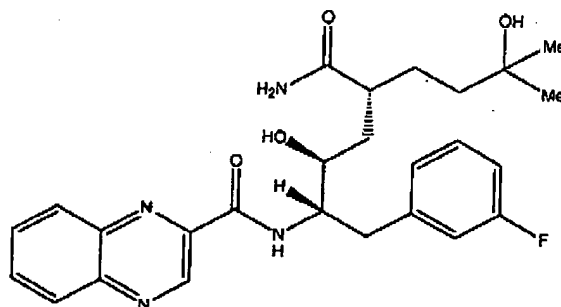
VI. Claims 1-14 Are Novel Over WO '167

Claims 1-14 stand rejected under § 102(b) over WO '167. Applicants respectfully ~~traverse~~ the rejection.

Present claim 1 is novel over WO '167 at least because WO '167 does not disclose each and every element of present claim 1. Claim 1 of WO '167 defines certain compounds of the general formula:



and the pharmaceutically acceptable salts of such compounds. Similar to WO '061, the Examiner asserts that the following species being exemplary of the disclosed genus of WO '167 anticipates the presently disclosed compounds:



Quinoxaline-2-carboxylic acid
[4(R)-carbamoyl-1(S)-(3-fluoro-benzyl)-2(S),7-dihydroxy-7-methyl-octyl]-amide

Present claim 1 is novel over WO '167 at least because the compounds disclosed by WO '167 are within the scope of the first proviso of present claim 1. Like WO '061, the compounds of the general formula of WO '167 have a hydroxyl group corresponding in position to the -O-L-R⁷

group of the presently disclosed general formula, which as discussed above, would result in L being a bond and R⁷ being hydrogen. Further, the species cited by the Examiner has a [(Me)₂OH]C-CH₂-CH₂- group corresponding in position to R³ of the presently disclosed general formula. To arrive at the [(Me)₂OH]C-CH₂-CH₂- group of WO '167, R³ would be (C₁-C₁₀)alkyl substituted with R⁸-L-O-, wherein L would be a bond and R⁸ would be hydrogen. Like WO '061, to arrive at the compounds disclosed by WO '167 including the species cited by the Examiner, L would be a bond and R⁷ and R⁸ would be hydrogen.

But, as mentioned above, present claim 1 has the proviso stating that if L is a bond, both R⁷ and R⁸ may not be hydrogen unless R¹ is (C₂-C₉)heteroaryl substituted with one or more groups of oxygen. As is apparent from the cited species, the quinoxaliny group of WO '167 is not substituted with one or more groups of oxygen. Indeed, none of the compounds disclosed by WO '167 have a (C₂-C₉)heteroaryl group substituted with one or more groups of oxygen when both R⁷ and R⁸ are hydrogen, which is required by the proviso of present claim 1. Thus, claim 1 is novel over WO '167 for at least this independent, patentably significant reason.

Claims 2-13 are novel over WO '167 at least by virtue of their direct or indirect dependency from novel claim 1. Claim 14 is novel over WO '167 at least by virtue of it defining an amount of a compound according to novel claim 1. Therefore, removal of the present rejection is respectfully requested at this time.

VII. Claims 1-4 and 8-11 Are Patentable Over US 6,403,587

Claims 1-4 and 8-11 stand rejected under obviousness-type double patenting over claims 1-5 and 11 of US 6,403,587. Without admitting or denying the legitimacy of the rejection, Applicants

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are submitting herewith a terminal disclaimer, which as the Examiner indicates at page 6 of the Office Action, can be used to overcome an obviousness-type double patenting rejection. As such, the present rejection is overcome.


VIII. Conclusion

Having addressed all outstanding issues, Applicants kindly request removal of all rejections and allowance of all pending claims at this time. To the extent the Examiner believes that it would facilitate allowance of this case, the Examiner is urged to call the undersigned at the number below.

Applicants believe that no fee is associated with the filing of this paper. However, to the extent a fee is due, the Commissioner is hereby authorized by this paper to charge any required fees or credit any overpayment to Deposit Account 16-1445.

Respectfully submitted,

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